

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,267	04/16/2001	Klaus Schumann	RO0234US	5473
7	590 10/21/2003		EXAMINER	
D Peter Hochberg			CHAN, SING P	
6th Floor 1940 East 6th Street			ART UNIT	PAPER NUMBER
Cleveland, OH 44114-2294			1734	

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

,						
	Application No.	Applicant(s)				
	09/763,267	SCHUMANN ET AL.				
Offic Action Summary	Examiner	Art Unit				
·	Sing P Chan	1734				
The MAILING DATE of this communication appears on the cover shet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REP THE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a re - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statu - Any reply received by the Office later than three months after the mailier earned patent term adjustment. See 37 CFR 1.704(b). Status		mely filed ys will be considered timely. n the mailing date of this communication. ED (35 U.S.C. § 133).				
1) Responsive to communication(s) filed on						
<u>'_</u>	This action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 13-19 is/are pending in the applicat	tion.					
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>13, 16, 17, and 19</u> is/are rejected.						
7)⊠ Claim(s) <u>14,15 and 18</u> is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers O) The appeir is objected to by the Everyiner						
9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) ☐ The proposed drawing correction filed on <u>06 November 2002</u> is: a) ☐ approved b) ☐ disapproved by the Examiner						
If approved, corrected drawings are required in reply to this Office action.						
12)☐ The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a)⊠ All b)□ Some * c)□ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)						
Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal	ry (PTO-413) Paper No(s) Patent Application (PTO-152)				

DETAILED ACTION

Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 13, 16, 17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted prior in view of Doering, Jr. (U.S. 3,813,846).

Regarding claim 13, the admitted prior discloses a method for producing hot sealed packs for TTS. The method includes the steps of feeding two laps in line with the heated sealing heads with the first head operating at a temperature of 200 °C, which is above the melting point of the polymer laps and the second head at a temperature of 70°C, which is below the melting point of the polymer laps, bond the laps together with heated sealing heads with their polymer layers lying against each other with pressure and heat. (Specification, Page 1, lines 9-34 and table on page 7) However, the admitted prior does not disclose the heated sealing heads includes two or more contact area and advancing the pack material from the first contact area to the second contact area for additional heat sealing. However, heated sealing heads with two or more contact area and advancing the pack material into additional contact areas for additional sealing are well known and conventional as shown for example by Doering, Jr. Doering, Jr. discloses a method of sealing a tray material, i.e. packing material, using a heated sealing mechanism with multiple projections, i.e. contact areas which are

Art Unit: 1734

considered to be identical, and moving the material through four sequential sealing operation with heat and pressure to form good seal with high throughput. (Col 4, lines 20-43)

It would have been obvious to one skilled in the art at the time the invention was made to provide a heated sealing mechanism with multiple identical contact areas and moving the material through sequential sealing operation with heat and pressure as disclosed by Doering, Jr. in the method of the admitted prior art to provide a good seal with high throughput.

Regarding claim 16, the admitted prior art does disclose the weldable polymer layer comprises high density polyethylene. (Specification, Page 1, lines 9-17)

Regarding claim 17, the admitted prior art does disclose the temperature of the first heated sealing head is set at 200 °C. (Specification, Page 1, lines 29-32)

Regarding claim 19, the admitted prior art does discloses the weldable polymer layer comprises polyacrylonitrile. (Specification, Page 1, lines 9-17)

Allowable Subject Matter

- 3. Claims 14, 15, and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 4. The following is a statement of reasons for the indication of allowable subject matter: The claims recite a method of producing hot-seal packs for transdermal therapeutic systems. The method includes transporting two laps with weldable polymer layer lying against the laps in a predetermined cycle through a sealing unit, pressing the

Application/Control Number: 09/763,267 Page 4

Art Unit: 1734

laps together at the second sealing station with the temperature of first heated sealing tool or head is set above the melting temperature of the polymer layer at 169°C for HDPE or 200°C for polyacrylonitrile, the temperature of the second heated sealing tool or head is set below the melting temperature of the polymer layer at 65°C for HDPE or 80°C for polyacrylonitrile, while the first area of the laps is being seal at the second sealing station, the second area of the laps is being seal at the first sealing station, advancing the second area of the laps to the second sealing station, and repeat the sealing cycle. Doering, Jr. discloses a method of sealing a tray material, i.e. packing material, using a heated sealing mechanism with multiple projections, i.e. contact areas which are considered to be identical, and moving the material through four sequential sealing operation with heat and pressure to form good seal with high throughput. (Col 4, lines 20-43) However, Doering, Jr. does not disclose the temperature of first sealing tool or head is set above the melting temperature of the polymer layer at 169°C for HDPE or 200°C for polyacrylonitrile, the temperature of the second heated sealing tool or head is set below the melting temperature of the polymer layer at 65°C for HDPE or 80°C for polyacrylonitrile as search of the prior art of record did not disclose reference or references in combination with the recited features.

Response to Arguments

5. Applicant's arguments with respect to claims 13, 16, 17, and 19 have been considered but are most in view of the new ground(s) of rejection.

Application/Control Number: 09/763,267 Page 5

Art Unit: 1734

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sing P Chan whose telephone number is 703-305-3175. The examiner can normally be reached on Monday-Friday 7:30AM-11:15AM and 12:15PM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 703-308-3853. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Application/Control Number: 09/763,267 Page 6

Art Unit: 1734

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Chan Sing B

RICHARD CRISPINO SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1700